EXHIBIT 7

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, SS.

SUPERIOR COURT DEPARTMENT
CIVIL ACTION NO. 03-5028-B

KARLA SAWYER, LINDA PAUL, JEANNIE ROSE AND JOYCE PALOMBA,
Plaintiffs

v.

INDEVUS PHARMACEUTICALS, INC., f/k/a INTERNEURON PHARMACEUTICALS, INC.,
Defendant

PLAINTIFFS' OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiffs, Karla Sawyer, Linda Paul, Jeannie Rose and Joyce Palomba (collectively referred to as "plaintiffs"), oppose Indevus Pharmaceuticals, Inc.'s ("Indevus") motion for summary judgment. The Complaint was timely filed and is not barred by G.L. c. 260, §§ 2A or 5A, the Massachusetts statutes of limitation that apply to this action.

Background

Plaintiffs seek to recover damages for valvular heart disease and/or pulmonary hypertension caused by their ingestion of the pharmaceutical diet drug dexfenfluramine ("Redux"), which was researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold by Indevus under the brand name Redux™ ("Redux").

Redux, developed by Indevus as an appetite suppressant, caused countless users, including plaintiffs, to sustain serious and sometimes fatal injuries including valvular heart

disease ("VHD"), primary pulmonary hypertension ("PPH") and secondary pulmonary hypertension. Plaintiffs allege that their ingestion of Redux caused them to suffer valvular heart disease and related illnesses.

More specifically, plaintiffs allege that both during the initial submission of its Redux New Drug Application ("NDA") and thereafter, Indevus withheld, mischaracterized and actively misrepresented reports and information in its possession which directly related to the risk of developing VHD and pulmonary hypertension. Indevus thereby misled the public, the Federal Food and Drug Administration ("FDA"), the medical community and plaintiffs, resulting in plaintiffs having received no or inadequate warnings regarding the true risks associated with ingesting Redux (See Complaint).

Introduction

Redux was removed from sale in the United States on September 15, 1997, following publication of research which disclosed the high incidence of heart damage suffered by consumers of the drug. For nearly two decades prior to the removal of Redux[1] from the United States market, Indevus, its principals, and its joint venture partner Wyeth (f/k/a American Home Products) concealed from the public the fact that Redux could cause valvular heart disease. When Dr. Heidi Connolly and the Mayo Clinic finally published a report in July 1997, confirming what the diet drug manufacturers knew all along – that as many as 30% of all diet drugs users may develop valvular heart disease – the diet drugs manufacturers went into full damage control mode. Wyeth spent over $90,000,000 to fund studies aimed at demonstrating

[1] Redux is the trade name for dexfenfluramine sold in the United States. Dexfenfluramine is the d-isomer of fenfluramine (collectively referred to as the "diet drugs"), which was sold as Pondimin in the United States. Each dose of fenfluramine contains a ½ dose of dexfenfluramine. As a result, the health and safety information related to either product is equally applicable to both products.

that the diet drugs did not carry an appreciable risk of causing VHD. That effort generated headlines such as "Study: No Heart Damages from Diet Drugs" in media throughout the country.

Compounding the uncertainty created by these conflicting public reports was the fact that VHD is not a self-evident or inherently recognizable injury. VHD is often asymptomatic. When the disease does cause symptoms, they are typically those such as fatigue and shortness of breath that can be associated with many different maladies. Thus, diet drug users such as the plaintiffs had no inherent way of knowing whether they had been injured by their use of the diet drugs.

To determine whether a diet drug user has developed VHD, he or she must undergo a medical procedure known as an echocardiogram. However, for a number of reasons, including the expense involved in performing that procedure, many authoritative sources, such as the federal government, medical societies, and the diet drug manufacturers themselves, agreed that diet drug users should not get an echocardiogram unless they were advised to do so by a physician. Only then could a diet drug user determine, through the exercise of reasonable diligence, whether he or she had been injured by the diet drugs.

The plaintiffs in this case all took reasonable measures to determine whether they had been injured as a result of ingesting the diet drugs – by consulting with their physicians. Plaintiffs Karla Sawyer, Linda Paul and Jeannie Rose all ingested Redux in 1996 and 1997. *See* Affs. of Karla Sawyer, Linda Paul and Jeannie Rose ¶ 1 (attached as Exs. 1-3 respectively). Plaintiff Joyce Palomba ingested Redux in 1996. *See* Aff. of Joyce Palomba ¶ 1 (attached as Ex. 4). Based on what was being reported in the media, Karla Sawyer's prescribing physician ordered an echocardiogram for her. The echocardiogram did not reveal any appreciable regurgitation at the time, and Ms. Sawyer's physician told her that her heart was fine. Ex. 1, Aff. of Karla Sawyer ¶ 4.

In each year after they ingested Redux, the Plaintiffs consulted with their physicians. *See* Exs. 1-4, Sawyer, Palomba, Paul and Rose Affs. ¶ 2. During those consultations, the plaintiffs underwent physical examinations during which their physician listened to their hearts to determine whether they had any indication of heart damage. *Id.* ¶ 3. None of the plaintiffs was advised by her physician that she had valvular heart disease or any other injury associated with her use of Redux. *Id.* ¶ 4. To the contrary, each of the plaintiffs was informed by her doctor that her heart sounded fine. *Id.*

Furthermore, none of the plaintiffs, with the exception of Karla Sawyer, was advised by her physician to have an echocardiogram. Palomba, Paul and Rose Affs. ¶ 5. Had they been so advised, they would have undergone the procedure. *Id.* Plaintiff Sawyer was advised to have an echocardiogram in 1997. After submitting to the procedure, she was advised by her physician that the results were normal and she had "nothing to worry about." Sawyer Aff. ¶ 4.[2]

Finally, in late 2001 and 2002 the plaintiffs had echocardiograms that revealed VHD. Until that time, the plaintiffs did not know, and could not reasonably have been expected to know, that they had suffered an injury as a result of ingesting the diet drugs.

ARGUMENT

1. Proper Application of Massachusetts' Discovery Rule Mandates a Denial of Indevus's Motion for Summary Judgment.

Defendant Indevus has moved for summary judgment contending that the plaintiffs' claims are untimely under G.L. c. 260, §§ 2A and 5A. As the moving party, Indevus has the burden under Mass. R. Civ. P. 56(c) of showing by credible evidence from affidavits and supporting material that there is no genuine issue of material fact, and that plaintiffs would be

[2] While an echocardiogram is the "gold standard" for diagnosing VHD, clinically significant VHD was not likely to be revealed on an echocardiogram performed in the first few years following plaintiffs' cessation of diet drug ingestion. *See* Aff. of George K. Massing, M.D. at ¶ 2 (attached as Ex. 5); see also In re: Diet Drugs, 1999 WL 673066 *11 (E.D. Pa. 1999) ("even minor valve damage may progress over time after cessation of diet drug use").

unable to prove their case at trial. *Smith v. Massimiano,* 414 Mass. 81, 85-86 (1993). In assessing the material presented, the court must credit the record with facts most favorable to the plaintiffs, and view any inferences that can be drawn from the underlying facts in the light most favorable to the plaintiffs. *Sullivan v. Boston Gas Co.*, 414 Mass. 129, 130 & n. 2 (1993). The plaintiffs' case need not be perfect, and a reasonable measure of doubt is tolerated. *Noble v. Goodyear Tire & Rubber Co.*, 34 Mass. App. Ct. 397, 402 (1993).

Summary judgment is not warranted in this case because there are genuine issues of material fact as to when the plaintiffs' causes of action accrued. Under Massachusetts law, a claim for negligence, breach of warranty or violation of c. 93A ordinarily accrues at the time of injury. *Taygeta Corp. v. Varian Associates, Inc.*, 476 Mass. 217, 229 (2002). However, Massachusetts has "recognized the unfairness of a rule that holds that the statute of limitations has run even before a plaintiff knew or reasonably should have known that she may have been harmed by the conduct of another." *Mohr v. Commonwealth*, 421 Mass. 147, 155-156 (1995) (internal quotation and citation omitted). For this reason, the Court adopted a discovery rule that effectively delayed the trigger for the running of the statute of limitations: "Where injury is present but not discernible, or an injury is recognized but its cause is not ascertainable, accrual of the cause of action is held to be in abeyance until the time when a modicum of knowledge supplants ignorance in the mind of the claimant, or may be reasonably imputed to her." *Lioji v. Massachusetts Bay Transportation Authority,* 28 Mass. App. Ct. 926 (1990).

Contrary to the defendant's assertion, mere notice of possibility of injury is not sufficient for a cause of action to accrue. A plaintiff must have reasonable notice of both the injury and of the cause of the injury. In *Bowen v. Eli Lilly & Co.,* 408 Mass. 204 (1990), the chief case upon which Indevus relies, the plaintiff was aware of her injury for 14 years before filing suit. For this

reason, the Supreme Judicial Court focused upon the second prong of the discovery rule – whether the plaintiff had reasonable notice of the *cause* of the harm. Unlike *Bowen* and related cases, plaintiffs were not aware of their injuries until recently and, hence, the *Bowen* analysis does not apply.

The courts have been particularly averse to requiring that plaintiffs file suit before the nature of their harm has become clear. "Not only does it offend fairness to require of claimants the gift of prophecy, cf. *Franklin v. Albert,* 381 Mass. at 618, but it is unsound judicial policy to encourage the initiation of law suits in anticipation that a grave disease will manifest itself pendente lite." *Gore v. Daniel O'Connell's Sons, Inc.*, 17 Mass. App. Ct. 645, 648 (1984). In its motion for summary judgment, Indevus runs afoul of this cautionary directive by seeking to impose upon plaintiffs a standard that would require that they file suit before being aware that they had suffered appreciable harm. That is not the law in Massachusetts.

Applying the discovery rule to claims arising from exposure to an allegedly toxic substance, the Supreme Judicial Court has held that a plaintiff's claim does not accrue until the plaintiff knows or reasonably should have known that he or she has been injured as a result of the defendant's conduct. *Olsen v. Bell Telephone Laboratories, Inc.*, 388 Mass. 171 (1983). "The cause of action does not accrue until the plaintiff learns or reasonably should have learned that he has been injured by the defendant's conduct both for negligence and breach of warranty in the products liability context." *Vigeant v. Zimmer, Inc.* 612 F. Supp 1043, 1045 (D. Mass. 1985) quoting *Fidler v. Eastman Kodak*, 714 F.2d 192, 196-97 (1st Cir. 1983) (failure of physician to inform patient that prosthesis had broken); *see also Pedraza v. Shell Oil Co.*, 724 F. Supp. 1, 5 (D. Mass. 1989) (applying discovery rule to claims arising from exposure to toxic substance); *Errichiello v. Eli Lilly and Co.*, 618 F. Supp 484, 486 (D. Mass. 1985) (applying discovery rule

to claim for injury from exposure to diethylstillbestrol (DES)). Thus, in a case such as this, where the injury alleged by the plaintiffs is not one that is apparent, obvious or inherently knowable, the statute of limitations does not begin to run until the plaintiff knows or reasonably should know that he or she has been injured as a result of the defendant's conduct.

"[T]he question when a plaintiff knew or should have known of his cause of action is one of fact which in most instances will be decided by the trier of fact." *Riley v. Presnell,* 409 Mass. 239, 240 (1991). Since there is abundant evidence in the record that plaintiffs did not discover and could not reasonably have discovered their injuries until within three years (or four years in the case of their c. 93A claims) prior to filing this action, Indevus's motion must be denied.

As will be discussed below, the only evidence in the record regarding plaintiffs' conduct prior to their ultimate diagnosis of VHD is that they did exactly what the Food and Drug Administration, the Department of Health and Human Services, the American College of Cardiology, the American Heart Association, and even the diet drug manufacturers themselves said should be done in order to determine whether they were injured - they consulted with their physicians. In so doing, the plaintiffs did not learn and could not reasonably have discovered that they had developed VHD until late 2001 and 2002, well within the three or four year window for filing suit.

The cases relied upon by Indevus are factually distinguishable because, unlike here, the plaintiffs in those cases were aware of their injuries long before the expiration of the limitations period. For example, in *Bowen, supra,* the plaintiff did not file a complaint until 14 years after notice of a tumor. Similarly, in *Martinez v. Sherwin Williams Co.*, 50 Mass App. Ct. 908 (2000), the plaintiff experienced injury in the form of numerous symptoms between 1985 and 1990 but did not initiate suit until 1995. See also *Lareau v. Page*, 840 F.Supp 920 (D. Mass. 1993),

affirmed, 39 F.3d 384 (1st Cir. 1994) (ruling that suit filed in 1990 was time-barred where plaintiff suffered injury in 1984 in the form of severe headaches and a grand mal seizure).

For similar reasons, the defendant's focus upon the publicity surrounding the withdrawal of Redux from the market is also misdirected. Even assuming that plaintiffs became aware that they had unwittingly used a potentially dangerous drug, this awareness did not put any of them on notice that they had an actionable claim until they had evidence of appreciable harm. Although the plaintiffs were examined by their physicians repeatedly from 1997 onwards, the first indication of injury did not become manifest until 2001 or 2002. It was only then that each of the plaintiffs acquired the requisite knowledge of ascertainable harm that triggered the limitations countdown.

2. Disputed Issues of Material Fact Preclude Summary Judgment

The plaintiffs filed this action on December 11, 2003. *See* Ex. Complaint. Thus, the question before the Court is whether Indevus has demonstrated, as a matter of law, that the plaintiffs knew or should have known that they had developed VHD prior to December 11, 1999 (with respect to plaintiffs' claim under c. 93A), or December 11, 2000 (with respect to their remaining claims).

As noted above, Redux was withdrawn from the market in the United States on September 15, 1997. Contrary to the defendant's suggestion, the information disseminated in the public domain following the withdrawal of the diet drugs from the market conflicted on whether or not the diet drugs caused VHD. While there were some reports in the media that linked the diet drugs to VHD, many stated just the opposite. For example:

- USA TODAY, April 1, 1998, headline read: "Study: No Heart Damage from Diet Drugs"

- CNN Interactive website in April 1998 stated: "Report: Diet Drug Redux May Not Cause Heart Problems"
- USA Today, November 1998, headline read: "Diet Drugs' Impact on Heart Still Hazy"

See public reports related to diet drugs attached hereto as Exs. 6-8.

The confusion over whether there was a link between diet drugs and VHD created by conflicting reports in the media was compounded by the fact that VHD was often asymptomatic in its initial stages and frequently silent on auscultation. *See ACC/AHA Guidelines for the Clinical Application of Echocardiography,* at 1692 attached as Ex. 9. Diet drug users, including the plaintiffs in this case, did not experience a sudden or recognizable injury upon ingesting Redux. *See* Exs. 1-4, Sawyer, Palomba, Paul and Rose Affs. ¶¶ 1, 4. The injury, if any, was a silent stalker and thus "inherently unknowable" to the diet drug user.

a. Plaintiffs Acted Reasonably in Inquiring About Their Injuries

There is no basis for Indevus to argue that the plaintiffs' duty of inquiry required them to obtain an echocardiogram. As discussed below, the class notice, the media reports, Wyeth's own experts, federal governmental health agencies and leading medical associations advised persons exposed to diet drugs to consult with their doctor, not to obtain an echocardiogram. Even if the Court should conclude, despite all the evidence to the contrary, that plaintiffs had an obligation to obtain an echocardiogram, there remains a material issue of fact as to whether an early echocardiogram would have revealed FDA positive heart valve disease.

To the contrary, the evidence offered by the plaintiffs establishes that had they obtained an echocardiogram between 1997 and 2000, it most likely would not have revealed FDA positive heart valve disease, even though they were later discovered to have that condition. *See* Ex. 5 , Aff. of George K. Massing, M.D. at ¶ 2. That evidence is consistent with Judge Bechtle's

findings in PTO 1415 in which he recognized that diet drug users' claims were not uniformly time-barred because their injuries were not actionable until they progressed to a more serious level in the future. *See* Ex. 10, *In re Diet Drugs*, (U.S.D.C., E.D. Penn.), Memorandum and PTO No. 1415 at 42.

Moreover, on the issue of whether a person should reasonably have discovered his or her injury immediately upon cessation of diet drug use, Judge Bechtle's findings in PTO 1415 specifically concluded that a diet drug recipient's injuries may be asymptomatic and, therefore, not discoverable until some later date. *See* PTO 1415 at 42. This is in fact what occurred to Karla Sawyer. *See* Ex. 1, Sawyer Aff. at ¶4. Indevus argues that plaintiffs' claims "are not saved by the discovery rule because valvular heart disease associated with diet drug use is not a latent injury." *See* Indevus's memorandum at 2. In making this argument, Indevus relies upon PTO 1415. However, PTO 1415 explicitly recognized that injuries resulting from the ingestion of diet drugs could be "asymptomatic" and may not be "discoverable" until sometime in the future. *See* PTO 1415 at 42.

There is also absolutely no evidence in this case that the plaintiffs' doctors would have discovered and informed the other plaintiffs besides Sawyer that they had valvular heart disease. To the contrary, the evidence in this case is that these plaintiffs did visit their physicians, yet their physicians failed to detect their injury on auscultation. In the exercise of their professional judgment, the plaintiffs' physicians chose not to refer the plaintiffs out for an echocardiogram, a costly procedure that ordinarily requires a prescription or referral from a medical doctor.

The physicians' reluctance to order an echocardiogram may have been due to the fact that it was not required for any, and not even indicated for many, diet drug users, and because significant valvular regurgitation may be silent on auscultation. *See* Exs. 11 & 12, Depo. of

Lawrence Cohen, M.D at 155 & 159, and Cohen Report at ¶ 26. Dr. Cohen, Wyeth's expert witness testified that "where a patient has presented with a history of exposure to fenfluramine, Redux, Pondimin, that doctor should not send that patient out for an echocardiogram. . . . .It's not good medicine." *See also,* Ex. 9, *ACC/AHA Guidelines for the Clinical Application of Echocardiography,* at pp. 1692 ("significant [valvular] regurgitation may be silent on auscultation… Because the finding of clinically silent valvular regurgitation in an asymptomatic patient carries an unknown significance, performance of Doppler echocardiography to exclude valvular heart disease . . . is not indicated."); *See* Ex. 13, Aff. of Bridgette Hampton, M.D. at ¶ 7 ("The standard of care in the medical community for treating patients who formerly ingested [diet drugs] has never been to automatically refer those patients for an echocardiogram.").

b. Karla Sawyer's 1997 Echocardiogram Did Not Reveal Injury.

Karla Sawyer's example perfectly demonstrates this point. Her 1997 echocardiogram did not reveal the presence of any significant valvular regurgitation. *See* Exhibit 14, Echocardiograms of Karla Sawyer. Certainly, this finding did not place Karla Sawyer or her physicians on notice that she had suffered a valvular injury as a result of her ingestion of diet drugs. Even Indevus does not claim that her 1997 echocardiogram showed an appreciable injury. In footnote 8 of its memorandum, Indevus suggests that the findings of the 1997 echocardiogram indicate that Ms. Sawyer was not and could not have been injured as a result of the ingestion of diet drugs. This assertion is based upon Judge Bechtle's conclusion in PTO 1415 that diet drug induced VHD was not a latent disease.

Indevus misses the point, and its reliance upon PTO 1415 is again misplaced. The fallacy of Indevus's argument regarding Ms. Sawyer's 1997 echocardiogram is its failure to recognize that diet drug induced VHD is a pathological disease, noted by the encasing of the valve tissue in

a white plaque like substance, resulting in myxoid type changes in the valve structure. Dr. Heidi Connolly, working at the Mayo Clinic, informed Wyeth and its partners of her finding to this effect in late February-early March 1997, and made her report and findings public on July 8, 1997. *See* Ex. 15, Connolly, et al., *Valvular Heart Disease Associated With Fenfuramine-Phentermine,* NEJM, 337:9, 581-588 (1997). These pathological changes to the actual valve tissue were further documented and explained by renowned cardiac pathologist Dr.Andrew S. Wechsler. *See* Ex. 16, Weschler, *Operation for anorexigen-associated valvular heart disease*, JTCS (October 2001).

It is this pathological injury that ultimately leads to the regurgitation that can be detected on an echocardiogram. The pathologic changes make it more difficult for the valves to operate properly and close completely, eventually resulting in regurgitation. *See* Exs. 15 and 16.

The other major fallacy in Indevus's argument is its failure to recognize that valvular regurgitation is a progressive disease at all stages. See Ex. 17, Raichlen, et al, *Abstract- Risk Factors For Progression of Mild and Moderate Regurgitation-Progression;* Ex. 18, Padial, et al, *Doppler Echocardiographic Assessment of Progression of Aortic Regurg* – Am.J.Cardio. 80 (306-314) at 306 (1997);. (Patients with mild and moderate AR slowly progress to the symptomatic phase; AR is a progressive disease, even in patients with mild AR, and it is not possible to predict which patients will progress for any degree of AR). The common understanding in the medical community is that "regurgitation begets regurgitation."[3] Therefore, just because regurgitation is not reported by echocardiogram does not mean that the pathological

[3] This fact was recognized by Indevus, Wyeth, Class Counsel and the MDL Court in approving the National Class Action Settlement, which allowed persons exposed to diet drugs until January-July of 2003 to receive an echocardiogram which first demonstrated at least mild mitral regurgitation (a condition which is not considered FDA positive valve disease); and if those persons condition progresses in the future, through the year 2015, they may apply for more benefits available to those with FDA positive injuries

injury to the valve tissue has not already occurred. Nor does it mean that the injury will not continue to progress in the future, which is exactly what has happened to Ms. Sawyer.

An analogous example is the rusty door hinge. After the hinge is exposed to water a slight buildup of rust begins inside the hinge. The rust cannot be seen because it is inside, and it cannot be heard because the hinge has not begun to squeak. Although rust is present, it is not detectable. However, over time the rust gets worse. After a few years the door may have to be pushed a little harder to close. A repairman may inspect it and find nothing of concern. Then a little while later, the rust progresses and the door stops shutting all the way. Maybe it gets even tougher to close the door, until finally the hinge must be replaced.

Valve disease works the same way. The initial pathological injury may not result in detectable regurgitation, but the disease process may be there. However there is no way to know, until an echocardiogram shows FDA positive valve disease. At that stage, instead of facing a hinge replacement, you are facing open-heart valve replacement surgery.

The fact that an echocardiogram conducted in 1997 may not have demonstrated significant regurgitation is specifically demonstrated by a case study published in 1999 in the Annals of Thoracic Surgery. *See* Ex. 19, Prasad, et al, *Cardiac Allograft Valvulopathy- A Case of Donor-Anorexigen-Induced Valvular Disease,* Ann. Thorac. Surg., 68:1840-41 (1999). In that case report, a organ donor, who had previously been exposed to diet drugs, was admitted to the hospital with a myriad of non-cardiac related symptoms, and subsequently passed away from an intracranial aneurysm. A transesophogeal echocardiogram ("TEE"), a more invasive procedure that produces a better echocardiographic image of the heart and any regurgitation that might be present, was performed to assess for transplant eligibility. The TEE revealed only **"trivial mitral regurgitation,"** but with **"mitral valve thickening"** and **"poor coaptation of mitral**

valve leaflets," and the heart was approved and harvested to be transplanted in a person on the heart transplant list. *See id.* at 1840. During the transplant, the thoracic surgeons noticed and removed multiple lesions from the valve tissue of the donor heart, and then completed the heart transplant procedure. *See id.* A TEE was then performed on the recipient patient, which revealed only trivial regurgitation. *See id.* The removed lesions were pathologically examined, and revealed "a glistening appearance with proliferating myofibroblasts and associated fibrinous vegetation," a finding essentially identical to the findings reported by Connolly and Hutchins in their descriptions of diet drug induced valvulopathy. *See id.* Remarkably, follow-up echocardiograms on the heart recipient revealed that the mitral regurgitation progressed from trivial to moderate, even after removal from the donor's body who had been exposed to the diet drugs. *See id.*

The authors of this case report noted in their comments, "**It was striking that routine transthoracic echocardiography estimated the valvular pathology as "mild," and thus underestimated the true pathological extent of valvular disease which was noted at surgery.**" *Id.* at 1841. Significantly, the 1997 echocardiogram report for Karla Sawyer also demonstrated "mild mitral leaflet thickening" with "insignificant mitral regurgitation" just as the TEE on the donor heart had revealed. *See* Ex. 14, Echocardiograms of Karla Sawyer. In fact, three echocardiograms performed by Dr. Cerel on Ms. Sawyer in 2003, all revealed the same "**mitral valve thickening**" and "**malcoaptation of the valve leaflets**" as the TEE of the donor heart in the Ochsner case report. *See id.* Only now, since being diagnosed in December 2002, is Ms. Sawyer suffering from severe mitral regurgitation. [4]

[4] On Ms. Sawyers' December 9, 2003, echocardiogram, the mitral regurgitation was described clinically as moderate, but still at a 2-3+ level as described by the other echos in 2003. Remarkably, from the first echo taken in February 2003 until the most recent echo, the left atrial measurement increased from 4.7 cm to 5.7 cm. This "left atrial enlargement" as recognized by Dr. Cerel in his reports, likely resulted in the reduction of the clinical

The report authors also rejected the idea of regression of disease after cessation of diet drug exposure, noting that the disease progressed in the recipient who had no anorexigen exposure. *See id.* Significantly, the authors stated in their conclusion that "[e]arly valvulopathy may appear clinically mild [even on TEE] yet pathologically significant." *Id.* As demonstrated by that case report, it is quite possible to have diet drug induced valve disease, but have no way of knowing, even by echocardiogram.[5]

It is noteworthy that Indevus does not suggest that the plaintiffs' physicians' failure to discover valvular heart disease through auscultation, and their decision not to order an echocardiogram (or follow-up echocardiogram in Ms. Sawyer's case), was an unreasonable exercise of their professional judgment. Under these circumstances there is at least a genuine issue of material fact as to whether VHD was reasonably discoverable any earlier.

The plaintiffs' conduct must be examined from the perspective of the "reasonable person." As previously stated, under the Massachusetts discovery rule, a cause of action accrues when the plaintiff (i) knows or reasonably should know that she was harmed and (ii) knows or reasonably should know the cause of that harm. *Riley v. Presnell,* 409 Mass. at 243. "The

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description of the regurgitation from "Severe" in February 2003 to "Moderate" in December 2003. Mitral regurgitation is typically measured as a percentage of the size (area) of the regurgitant jet, compared to the size (area) of the left atrium, so that when the left atrium size increases, due to increased pressures caused by the severe regurgitation, the percentage of the regurgitation compared to the left atrial area may decrease slightly. *See* Ex.20, National Class Action Settlement. This change, however is not a good thing, as such remodeling of the heart is a devastating effect of significant valvular regurgitation, likely to lead to congestive heart failure and other serious cardio-pulmonary impairments, often necessitating valve replacement surgery.

[5] There are many additional factors that would explain why the 1997 echocardiogram report of Ms. Sawyer would not have indicated an injury, including but not limited to: 1) an erroneous report; 2) an overly conservative interpretation by the reading cardiologist; 3) Ms. Sawyer's body habitus at the time of the echocardiogram - medical literature supports the proposition that echocardiograms conducted in obese individuals often result in an underestimation of the amount of regurgitation present due to the technical limitations of the echocardiographic equipment; 4) the presence of other medical factors at the time of the echocardiogram, such as lowered blood pressure, medications taken at the time that would mask the amount of valvular disease present and reduce the amount of valvular regurgitation present at that time. In short, the 1997 echocardiogram report was inconclusive. As demonstrated above, many factors could have resulted in an echocardiogram report that either failed to detect valvular disease or regurgitation, or actually underestimated any regurgitation that was detected.

reasonable person who serves as the standard in this evaluation ... is not a detached outside observer assessing the situation without being affected by it." *Id.* at 245. "Rather, it is a reasonable person who has been subjected to the conduct which forms the basis for the plaintiff's complaint." *Id.; see also Bowen v. Eli Lilly & Co., Inc.,* 408 Mass. at 208 (noting that the court should look at "a reasonable person in the position of the plaintiff").

The plaintiffs' reliance upon the professional judgment of their physicians, as well as the advice of the U.S. Government, all major medical societies, and of the National Class Action Settlement itself, creates an issue of fact as to the reasonableness of their conduct in determining whether they had suffered harm from the ingestion of Redux. *See Zamboni v. Aladan Corp.,* 304 F. Supp. 2d 218, 226 (D. Mass. 2004) (holding that plaintiff's reliance upon diagnosis of physicians created issue of fact precluding summary judgment on grounds of discovery rule). *See also Lindsay v. Romano*, 427 Mass. 771, 775 (1998) (holding that plaintiff reasonably relied on numerous medical opinions that failed to establish link between the defendant's conduct and the plaintiff's injury); *Castillo v. Massachusetts General Hospital,* 38 Mass. App. Ct. 513, 516 (1995) (holding that there was no basis for concluding that reasonable person would have discovered harm until physician interpreted his medical test results).

In this case, each of the plaintiffs did exactly what the defendant and other authorities suggested that she do – she consulted with her physician. Based on what was being reported in the media, Karla Sawyer's prescribing physician ordered an echocardiogram for her in 1997, which did not reveal any appreciable regurgitation at the time, and specifically told Ms. Sawyer that her heart was fine. Ex. 1, Aff. of Karla Sawyer ¶ 4. In each year after they ingested Redux, the plaintiffs consulted with their physicians. During those consultations, the plaintiffs underwent physical examinations during which their physician listened to their hearts to

determine whether they had any indication of heart damage. *Id.* ¶ 3. However, none of the plaintiffs were advised by their physicians that she had VHD or any other injury associated with her use of Redux. *Id.* ¶ 4. To the contrary, each of the plaintiffs was informed that her heart sounded fine. *Id.*

Furthermore, none of the plaintiffs, with the exception of Karla Sawyer, was advised by her physician to have an echocardiogram. *See* Exs. 2-4, Palomba, Paul and Rose Affs. ¶ 5. Had she been so advised, she would have undergone the procedure. *Id.* [6]

In this case, Indevus has failed to present any evidence that even one of the plaintiffs failed to visit her physician to obtain an evaluation following her use of diet drugs. So too has Indevus failed to present any support for the proposition that such a visit would have necessarily resulted in an echocardiogram that necessarily would have revealed FDA positive heart valve disease.

Plaintiff Sawyer had a second echocardiogram in December 2002. Plaintiff Palomba had an echocardiogram in June 2002. Plaintiff Paul had an echocardiogram in May 2002. Plaintiff Rose had an echocardiogram in November 2001. Following those echocardiograms, each of the plaintiffs learned for the first time that she was suffering from clinically significant VHD. *See* Exs. 1-4, Sawyer, Palomba, Paul and Rose Affs. ¶¶ 1, 4.

c. Indevus's Selective Media Reports Do Not Trigger The Running of The Statute of Limitations.

Indevus seeks to have the Court trigger the running of the statute of limitations merely upon a jumble of media reports. Essentially, Indevus seeks the imposition of a judicially-enforced Catch-22 in which the plaintiffs' cause of action would accrue before the plaintiff had

[6] While an echocardiogram is the "gold standard" for diagnosing VHD, clinically significant VHD was not likely to be revealed on an echocardiogram performed in the first few years following plaintiffs' cessation of diet drug ingestion. *See* Aff. of George K. Massing, M.D. at ¶ 2 (attached as Ex 5); *see also In re: Diet Drugs*, 1999 WL 673066 *11 (E.D. Pa. 1999) ("even minor valve damage may progress over time after cessation of diet drug use").

sustained, much less discovered, an appreciable injury. Apart from the lack of appreciable injury, there is also a significant question of material fact as to whether all the media reports taken together - not just the duplicative and self-serving subset filed with this court by Indevus - should have caused plaintiffs to secure an echocardiogram.[7] In fact, around the time of the drug withdrawal, the diet drug manufacturers commenced a public relations blitz in the hope of rehabilitating these deadly drugs. Beginning in 1997, as demonstrated in the very exhibits attached to Indevus's pleadings, and into 1998 and beyond, media reports downplayed or contradicted the risks of the diet drugs. These reports, and many others, are collected at Ex. 21 attached hereto. Such reports - particularly those regarding the alleged healing of injuries - could only have raised significant doubt in the minds of diet drug users as to whether the cause of action even existed.

Even the media excerpts submitted by the defendant are rife with mixed messages. Plaintiffs' Ex. 22 attached hereto is a table documenting the large number of misleading, confusing and even contradictory statements contained in the diet drug manufacturers' carefully culled media excerpts. When added to the clips the defendant chose not to share with the Court - such as the USA Today headline trumpeting "Study: No Heart Damage from Diet Drugs" - the effect on a reasonable plaintiff would be uncertain at best. This is particularly true in light of the admitted cost of the echocardiogram. As noted in Indevus's selected clips, echocardiograms were and are expensive: "the echocardiogram costs anywhere between eight hundred and a

[7] There were essentially three ways for a patient to obtain an echocardiogram. First and foremost, all major medical organizations, as well as Wyeth and Indevus, told diet drug consumers that they should see a doctor who would determine whether an echocardiogram was indicated, based on their symptomatology. Second, diet drug consumers could register for the AHP National Class Action Settlement Screening Program, which began in 2002, in which case they would be provided a free echocardiogram. Third, some lawyers contracted with board-certified cardiologist and echotechnicians to provide echocardiograms for potential clients. These echocardiograms were primarily provided between January 2002 and January 2003, which was the deadline imposed for having such an echocardiogram by the AHP (Wyeth) Class Action Settlement.

thousand dollars," ABC News reported in November 1997. Similar reports appeared on CNN and elsewhere.

Although Indevus argues that the diet drug publicity provided notice to plaintiffs of potential injury, it has been held that "the determination of whether a reasonable person would have discovered the information depends on various factors...[including] the *quality and quantity* of the information or publicity... ." (emphasis added) *Hopkins v. Dow Corning Corp.*, 33 F.3d 1116, 1123 (9th Cir. 1994) (holding that imputing knowledge was not appropriate where article and other lawsuits "were neither numerous nor notorious enough"). Additionally, the characteristics of a plaintiff have been found relevant. *See Bibeau v. Pacific Northwest Research Foundation Corp.*, 188 F.3d 1105, 1110 (9th Cir. 1999) (refusing to impute knowledge of widespread publicity because reasonable person in plaintiff's shoes might not have known about publicity). At a minimum, the diet drug manufacturers' dissemination of information in the nationwide media, which purported to refute the existence of a causal link between the ingestion of diet drugs and valvulopathy, created an issue of fact as to the reasonableness of the plaintiffs' conduct prior to their diagnosis of VHD.

Specifically, Indevus argues that "intense media scrutiny from September 15, 1997, through December 10, 1999, and through December 10, 2000" should have placed the plaintiffs on notice of their potential claims against Indevus and led to the discovery of their injuries. See Indevus's Memorandum of Law at 14. Indevus asks the court to draw the improper conclusion that, in light of the diet drug publicity that existed after the withdrawal of Redux from the market, plaintiffs were charged with the obligation, *as a matter of law*, to obtain echocardiograms that would have revealed that they suffered from FDA positive VHD. Contrary to what Indevus, leading medical organizations, and governmental health authorities advised

plaintiffs to do in order to determine whether they had suffered an injury related to their use of the diet drugs, Indevus now asks this Court to conclude *as a matter of law* that the exercise of reasonable diligence required plaintiffs to obtain an echocardiogram that would have revealed their injuries prior to December 10, 1999 (four years prior to the filing of their lawsuit based upon Plaintiffs' 93A claim) and/or December 10, 2000 (three years prior to the filing of their lawsuit based upon Plaintiffs' non-93A based claims).

As stated above, Indevus's argument ignores the undisputed evidence in this case - that plaintiffs did exactly what they should have done by consulting with their physicians who specifically examined their hearts and initially found nothing wrong. *See* Exs. 1-4, Affs. of Plaintiffs. There is a material and disputed question of fact as to whether any plaintiff had a legal obligation in light of her lack of symptoms, conflicting media reports, and the high cost of the echocardiogram procedure, to do more by seeking out and pay for such an expensive and potentially unnecessary diagnostic test when it was not recommended or ordered by her own physician.

3. Defendant's Arguments about Latency are Misplaced

Indevus's latency argument is irrelevant to the key issue before this court. The inquiry is when the plaintiffs reasonably should have discovered that they were harmed, and that inquiry is a question of fact. Here, plaintiffs have produced evidence to show that they acted with reasonable diligence to discover their injuries from the year they first ingested Redux until they discovered VHD through the echocardiograms. *See* Exs. 1-4, Sawyer, Palomba, Paul and Rose Affs. ¶¶ 1, 4. Indevus's contention that VHD is not a latent injury simply has no bearing on that inquiry. Indeed, Indevus's joint venturer, Wyeth, has made similar contentions in other cases, to

no avail. *See for example, Dykes v. Reeves*, No. 2:03CV121PG at 6 - 7 (S.D. Miss. Nov. 6, 2003) (attached as Ex. 23). The *Dykes* Court explained:

> Defendants strongly argue that the MDL litigation has determined that valvular heart disease is not a latent disease and as such the parties in this case are bound by such finding. The fallacy of Defendant's argument in this regard is that the issue is not whether or not the condition is latent, but whether . . . the condition should have been found with "reasonable diligence." That is the issue. The issue is not whether or not the condition is latent. Whether Plaintiff should have discovered her condition prior to June 21, 2000, is a fact question.

Dykes at 6-7.

While Plaintiffs disagree with Indevus's definition of latency as argued in its brief, "latency" or "non-latency" has no bearing on whether plaintiffs acted reasonably to discover the injuries.

Additionally, to the extent this Court chooses to consider the issue of latency to any extent, it should be noted that this issue is not identical to the issue of latency discussed by Judge Bechtle when he approved that National Class Action Settlement in PTO 1415. Nor was the issue "fully and vigorously litigated" in the prior action. *See In re Docteroff*, 133 F.3d 210, 215 (3d Cir. 1997) (for collateral estoppel to apply, the issue must have been fully and vigorously litigated in the prior action).

As a threshold matter, the National Class Action Settlement was a negotiated settlement in which both Wyeth and Class Counsel[8] agreed to a compromise. There was no vigorous litigation regarding latency, certainly not between Wyeth and Class Counsel. The affidavit of Dr. James Oury, a board-certified cardio-thoracic surgeon who was retained by "class counsel"

[8] As part of this agreement, Wyeth agreed to pay Class Counsel $200,000,000. That is in addition to the 9% assessment Class Counsel was to be awarded in individual or class settlements paid through the MDL. *See* Settlement Agreement at p. 141.

in this matter to testify on matters related to the association between the diet drugs and valvular heart disease, removes any doubt on this issue. Dr. Oury has testified that he informed class counsel that diet drug induced valvular heart disease is a latent injury. Oury aff. ¶ 2 (attached as Ex. 24). He explained, however, that "[f]or reasons I do not know, I was not asked by those lawyers to testify at the MDL hearing to approve the national class action settlement for diet drugs, but had I been asked to testify, I would have shared these same opinions with the Court." *Id.* ¶ 5.

During the fairness hearing, there was no sub-class counsel assigned to protect and litigate the rights of claimants whose injuries had not appeared and would not become manifest for a period of time following their exposure to diet drugs. Furthermore, it is apparent from Dr. Oury's affidavit that class counsel did not act to protect the rights of such claimants. To the contrary, class counsel elected not to present the MDL court with their own expert's opinion that diet-drug induced VHD is a latent disease. Because nobody represented or sought to protect the rights of claimants (including the plaintiffs in this case) who had yet to manifest injury, this Court cannot conclude that the plaintiffs are collaterally estopped from addressing the issue of latency. *See e.g., McCandless v. Merit Sys. Protection Bd.,* 996 F.2d 1193, 1198 (Fed.Cir.1993) (finding no collateral estoppel where party against whom collateral estoppel argument is made did not have full and vigorous representation of claims in prior litigation); *Martin v. United States,* 30 Fed.Cl. 542, 546 (Fed.Cl.1994); *Koppie v. Busey,* 832 F.Supp. 1245, 1255 (N.D.Ind.1992).

The MDL court's finding regarding the lack of latency is significant more for the *Amchem*-type problem it implicates, and for whether or not the class action settlement itself should be collaterally attacked for the failure to adhere to the due process rights of the claimants.

As discussed above, under Massachusetts law, the determination as to when the statute of limitations began to run on the plaintiffs' claims against Indevus does not turn on whether the plaintiffs did or did not, in fact, have valvular heart disease shortly after ingesting the diet drugs. Rather, the relevant inquiry is when, *in the exercise of reasonable diligence,* the plaintiffs should have discovered their injuries. It can hardly be said as a matter of law that the plaintiffs failed to act with reasonable diligence to discover their injuries any earlier than they in fact did.[9]

4. **Class Tolling Applies**

Although the Court need not reach this issue, the fact that the statute of limitations in this matter was tolled under the principle of equitable tolling provides an alternative and additional ground for the denial of Indevus's motion for summary judgment. *See American Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 554, 94 S.Ct. 756, 38 L.Ed.2d 713 (1974); *Crown, Cork & Seal Co. v. Parker*, 462 U.S. 345, 353-354, 103 S.Ct. 2392, 76 L.Ed.2d 628 (1983). Despite numerous pages in its brief on the class action tolling issues, Indevus fails to demonstrate either (1) that Massachusetts does not recognize class action tolling under *Amercan Pipe*; or (2) that plaintiffs' claims would not be covered by any class action filed in Massachusetts or in another jurisdiction.

Contrary to Indevus's arguments in its brief, Massachusetts *has* recognized the principles of class action tolling set out in *American Pipe* and *Crown Cork.* As stated by the Appeals Court in *Dicerbo v. Commissioner of the Dept.. of Employment and Training*, 54 Mass. App. Ct. 128, n.13 (2002), "as to putative class members who wish to intervene, the statute of limitations is

[9] Indevus also fails to effectively distinguish Judge Bartle's ruling in PTO 2710, an MDL decision wherein the MDL court correctly deferred to a particular state's discovery rule. See, e.g., *In re: Diet Drugs*, Memorandum and Pretrial Order No. 2710, attached hereto as Ex. 25 (ordering remand to state court in the District of Columbia because "there is a least a realistic possibility that the statute of limitations has been tolled by the discovery rule…"). The MDL court has held that despite the media and notice campaigns discussed in Wyeth's removal papers in other cases, there is a realistic possibility that the statute of limitations has been tolled by the discovery rule. *See* P.T.O. 2710 at 9 (attached as Ex. 25). Even more recently the MDL court has found that the date that a claimant's echocardiogram reveals injury, not the date of the withdrawal of the diet drugs from the market, is the date that triggers the commencement of the statute of limitations. *See* P.T.O. 3247 at 8 (attached as Ex. 26).

tolled upon the filing of the complaint," citing both *American Pipe* and *Crown Cork.*

The Supreme Judicial Court of Massachusetts has also adopted the holding of *American Pipe* in the context of class actions. *See Baldissari v. Public Finance Trust*, 369 Mass. 33 (1975). In *Baldissari*, the Court specifically stated:

> [W]e think he and others similarly situated may join in a class action to redress that injury and similar injuries caused by the same act or practice. Multiple demands for relief need not be filed on behalf of all the members of the class. If no reasonable tender of settlement is made in response to the first demand, further demands are not likely to serve any useful purpose and are not required. The modern class action is '**designed to avoid, rather than encourage, unnecessary filing of repetitious papers and motions.**' *American Pipe & Constr. Co. v. Utah*, 414 U.S. 538, 550, 94 S.Ct. 756, 765, 38 L.Ed.2d 713 (1974).

Id. at 707 (emphasis in original).

Defendant's only citation to Massachusetts law regarding class action tolling is totally inapposite to the issues presented here, and in no way stands for the proposition for which it is cited. *See Mass. Elec. Co. v. Mass. Comm'n Against Discrimination*, 375 Mass. 160, 165 n.2 (1978). Although Indevus cited *Mass. Elec.* for the proposition that Massachusetts does not recognize class tolling, the Court in that case merely decided that it did not need to reach that issue. In fact, by indicating that such a determination could be made, the *Mass Elec.* court implicitly recognized that Massachusetts had adopted the principles of *American Pipe.* Indevus's briefing on this issue misses the mark in framing the issue as whether Massachusetts would recognize class action tolling.[10] This issue has already been answered in the affirmative by the Supreme Judicial Court in *Baldissari.*

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[10] Indevus addresses this argument by discussing whether Massachusetts courts would certify a personal injury/Mass Tort class action. However, the question of whether a class is ultimately certified is not dispositive of the issue of whether potential class members' claims would be tolled until such time as certification was denied.

Acknowledging, at least by implication, that Massachusetts does in fact recognize class action tolling, Indevus spends much of its argument discussing potential limitations upon this principle that have been recognized by courts in other jurisdictions. Indevus fails, however, to cite to any Massachusetts case that has adopted any of those limitations. Specifically, Indevus fails to identify any Massachusetts case indicating that class action tolling would only apply (1) through the pending of the first filed class action; or (2) where the class was filed in Massachusetts; or (3) that subsequently filed claims would have to be filed within the Massachusetts savings clause; or (4) any of the other issues raised by Indevus in its brief. Though Massachusetts has recognized the principle of class action tolling for nearly thirty years, Indevus has failed to cite a single Massachusetts case recognizing any of the exceptions or limitations it asserts have been adopted in other jurisdictions.

Indevus's lengthy discussion of class action tolling is but a further attempt to complicate the issues facing the Court. Because Massachusetts does recognize class action tolling, the question is whether a class action exists or existed that would cover plaintiffs' claims against Indevus. If there is a class action that even arguably covers plaintiffs' claims, Indevus's motion for summary judgment must be denied.[11] Multiple class actions have been filed around the nation, including several federal class actions as well as two class actions in Massachusetts. In fact, class actions against Indevus have been certified in Pennsylvania and West Virginia that arguably would serve to toll some, if not all of plaintiffs' claims against Indevus.

[11] As Indevus admits, two class actions have been filed in Massachusetts that would arguably cover some if not all of plaintiffs' claims here. Certainly, the *Doherty* class action covered all of Karla Sawyer's claims, including her c.93A claim through April 27, 2000. Further, after April, 27, 2000, the class in *Doherty* was expanded to cover claims for everyone in the United States who ingested Redux, which would cover all of the plaintiffs' in this case. While the *Doherty* lawyers attempted to exclude personal injury claims in the class definition in the Motion for Class Certification, these limitations were never certified. In any event, as recognized by Indevus, the plaintiffs in this case are in no way limited in the claims they may bring against Indevus. It is therefore arguable that the April 27, 2000 class definition in *Doherty* would have continued to cover some of the claims of plaintiffs brought here including claims for economic injury under c. 93A and medical monitoring.

Again, plaintiffs need not rely upon class action tolling as it is clear that they have brought timely claims against Indevus, as described above.

CONCLUSION

Defendant Indevus's Motion For Summary Judgment should be denied. Viewing all disputed facts in a light most favorable to the plaintiffs, Indevus has failed to demonstrate that, as a matter of law, plaintiffs' claims are barred by the applicable statutes of limitation. More specifically, the issue of whether the plaintiffs acted with reasonable diligence in discovering their injuries is, at a minimum, a disputed issue of material fact that is a proper question for a jury.

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